

VACUUM-ASSISTED ELECTROPORATION DEVICES, AND RELATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Application No. 62/992,513, filed Mar. 20, 2020, the entire contents of which are incorporated herein by this reference.

TECHNICAL FIELD

[0002] The present invention relates to devices for gripping and deforming tissue with vacuum pressure, injecting fluid into the tissue, and electroporating the tissue with electrodes, as well as to systems and methods related to injecting or otherwise delivering fluid into the tissue and electroporating tissue.

BACKGROUND

[0003] In the 1970s, it was discovered that electrical fields could be used to create pores in cells without causing permanent damage to the cell. This discovery, termed electroporation (EP) made it possible for large molecules, small molecules, ions, and water to be introduced into a cell's cytoplasm through the cell wall. In some instances, electroporation can be used in topical treatments, such as head and neck cancer, to introduce chemicals and other compounds into the tumor. During these procedures, the patient may or may not be under general anesthesia so pain and involuntary muscle movement must be minimized.

[0004] Skin is a popular target for EP because it is easily accessed and contains a rich variety of immune cells suitable for delivery of a DNA vaccine. The natural immune function of skin and its high rate of cellular turnover typically leads to rapid, strong humoral responses to EP-enhanced DNA vaccine delivery. Skin is also capable of generating cellular immune responses following EP-enhanced DNA vaccine delivery. Due to its superficial nature, skin is suitable for minimally invasive or noninvasive EP.

[0005] Skeletal muscle is also a well-characterized target for electroporation-mediated (EP) delivery of DNA in vivo. Myocytes are capable of producing and secreting proteins for long periods of time, and it has been repeatedly demonstrated that EP enhanced DNA vaccinations into muscle are able to generate an immune response. However, applications of muscle EP DNA delivery are complicated by the variable thickness of subcutaneous fat, preventing a "one size fits all" approach since different fat thicknesses result in different needle penetration depths into the muscle tissue. Skeletal muscle, particularly in larger animals and humans, is typically unsuitable for minimally invasive or noninvasive EP techniques because of the insulating subcutaneous fat layer and the depth required to generate electric fields. Therefore, penetrating needle electrodes are most commonly used to perform EP in muscle.

[0006] Historically, adipose tissue (fat) has been viewed as an inert tissue primarily used to store energy in the form of lipid droplets. As such, only recently have EP-enhanced DNA procedures been directed to the adipose layer of tissue. However, recent studies have shown that subcutaneous fat actually serves many dynamic roles. Adipose tissue contains many stem cells and immune cells, and acts as an endocrine

organ by secreting numerous hormones, secretes many local signals, and contains an elaborate network of capillaries. Attempts to achieve in vivo transfection of adipose tissue have mainly been limited to surgical techniques that require the administrator to cut away and physically remove samples of the patient's skin to allow contact with the adipose tissue directly. These treatments are extremely invasive and are not suitable for clinical devices.

SUMMARY

[0007] According to an embodiment of the present disclosure, a device for vacuum-assisted in vivo electroporation of tissue includes a housing that defines a chamber and at least one opening into the chamber. A port extends through the housing and is remote from the at least one opening and is connectable to a vacuum source. The port is configured to communicate vacuum pressure from the vacuum source to the chamber. A plurality of electrodes are positioned within the chamber and are configured to deliver one or more electroporation pulses to a targeted portion of tissue extending through the opening and at least momentarily held in the chamber responsive to the vacuum pressure.

[0008] According to another embodiment of the present disclosure, a method of electroporating the tissue of a subject includes placing a chamber adjacent the tissue, applying vacuum pressure to the chamber, thereby drawing the tissue through an opening of the chamber and into contact with a plurality of electrodes extending along an interior surface of the chamber, and delivering one or more electroporation pulses through the plurality of electrodes to the tissue, thereby creating an electroporation field within the tissue.

[0009] According to a further embodiment of the present disclosure, a device for vacuum-assisted treatment of tissue includes a housing defining a chamber and at least one opening into the chamber. A first port extends through the housing and is remote from the at least one opening. The first port is connectable to a vacuum source, such that the first port is configured to communicate vacuum pressure from the vacuum source to the chamber. The device includes a jet-injection device that extends through a second port into the chamber. The second port is opposite the at least one opening. The jet-injection device is configured to deliver a jet injection of fluid to a targeted portion of tissue extending through the at least one opening and at least momentarily held in the chamber responsive to the vacuum pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] This patent application contains at least one drawing executed in color. Copies of this patent application with color drawing(s) will be provided by the Office upon request and payment of the necessary fee. The foregoing summary, as well as the following detailed description of illustrative embodiments of the present application, will be better understood when read in conjunction with the appended drawings. For the purposes of illustrating the structures of the present application, there is shown in the drawings illustrative embodiments. It should be understood, however, that the application is not limited to the precise arrangements and instrumentalities shown. In the drawings:

[0011] FIG. 1 is a diagrammatical view of an electroporation system that employs a vacuum-assisted electropora-